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jc135 U.S. PTO

PATENT

Atty. Docket No. ACS 48047 (3807.2)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Continuing Application under 37 CFR 1.60

Docket Number: 48047	Anticipated Classification of this Application: <u>Class</u> <u>Subclass</u>	Prior application: <u>Examiner</u> <u>Art Unit</u> C. Bennett 3307
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Box PATENT APPLICATION
ASSISTANT COMMISSIONER FOR PATENTS
Washington, D.C. 20231

This is a request for filing a [] continuation [X] divisional application under 37 CFR 1.60,
of pending prior Application No. 08/783,097, filed on January 14, 1997, of Lilip Lau, William M.
Hartigan and John J. Frantzen for EXPANDABLE STENTS AND METHOD FOR MAKING SAME.

[X] Enclosed is a copy of the prior application, including the oath or declaration as
originally filed.

I hereby verify that the attached papers are a true copy of prior Appln. No. 08/783,097, as
originally filed on January 14, 1997 and further that this statement was made with the knowledge
that willful false statements and the like so made are punishable by fine or imprisonment, or
both, under Section 1001 of Title 18 of the United States Code and that such willful false
statements may jeopardize the validity of the application or any patent issuing thereon.

[] Verified Small Entity Status form(s):
[] enclosed, [] will follow, [] filed in prior application and copy(s) enclosed.

[X] The filing fee is calculated below:

CLAIMS AS FILED IN PRIOR APPLICATION, LESS ANY CLAIMS
CANCELLED BY AMENDMENT BELOW.

For	Number filed	Number extra	Rate	Fee
Total Claims	18 - 20 =	0	X \$22.00	= \$ 0
Independent claims	2 - 3 =	0	X \$80.00	= \$ 0
Multiple Dependent Claim Fee			\$260.00	= \$
Basic fee				= \$ 790.00
Total of above Calculations =				= \$
Reduction by ½ for filing by small entity (Note 37 CFR 1.9, 1.27, 1.28)			Less	= \$
			TOTAL	= \$ 790.00

4. [X] A check in the amount of \$790.00 is enclosed.

5. [X] The Commissioner is hereby authorized to charge any additional fees which may be required in connection with this filing, or credit any overpayment, to Account No. 06-2425. A **duplicate** copy of this sheet is enclosed.
6. [X] Cancel in this application original claims 2-24 of the prior application before calculating the filing fee. (At least one original independent claim must be retained for filing purposes.)
7. [X] Amend the specification by inserting before the first line the sentence: --This is a [] continuation, [X] division, of U.S. Serial No. 08/783,097 filed January 14, 1997, which is a division of U.S. Serial No. 08/556,516 filed November 13, 1995, now U.S. Patent No. 5,603,721, which is a division of U.S. Serial No. 08/281,790, filed July 28, 1994, now U.S. patent No. 5,514,154, which
8. [] Transfer the drawings from the prior application to this application and abandon said prior application as of the filing date accorded this application. A duplicate copy of this sheet is enclosed for filing in the prior application file. (May only be used if signed by person authorized by Section 1.138 and before payment of base issue fee.)
- 8a. [X] New drawings [] formal [X] informal are enclosed.
- 8b. [] Priority of Application No. _____, filed on _____ in _____ is claimed under 35 U.S.C. 119.
- 8c. [] The certified copy has been filed in prior Application No. _____, filed _____.
9. [X] The prior application is assigned of record to ADVANCED CARDIOVASCULAR SYSTEMS, INC..
10. [X] A preliminary amendment is enclosed. (Claims added by this amendment have been properly numbered consecutively beginning with the number next following the highest numbered original claim in the prior application.)
11. [X] The power of attorney in the prior application is to:

Craig B. Bailey, 21,410; Richard A. Bardin, 20,365; Gilbert G. Kovelman, 19,552; and
John S. Nagy, 30,664

 (name and registration number)

all of 10877 Wilshire Blvd, Tenth Floor, Los Angeles, California 90024.

- 11a. [X] The power appears in the original papers in the prior application.
- 11b. [] Since the power does not appear in the original papers, a copy of the power in the prior application is enclosed.
- 11c. [X] Address all future communications to: John S. Nagy, Esq., FULWIDER PATTON LEE & UTECHT, LLP, 10877 Wilshire Blvd., Tenth Floor, Los Angeles, California 90024.

PATENT

Atty. Docket No. ACS 48047 (3807.2)

11d. ☒ Address all telephone inquiries to John S. Nagy, Esq., at the below listed telephone number. (May only be completed by applicant, or attorney or agent of record.)

4/6/98

(Date)

John Nagy

(Signature)

Address of signer:

John S. Nagy, Esq.

FULWIDER PATTON LEE & UTECHT, LLP

10877 Wilshire Blvd., Tenth Floor

Los Angeles, California 90024

Telephone No. (310) 824-5555

Facsimile No. (310) 824-9696

☐ Inventor(s)

☐ Assignee of complete interest

☒ Attorney or agent of record

☐ Filed under Section 1.34(a)

APPLICATION

of

LILIP LAU

WILLIAM M. HARTIGAN

JOHN J. FRANTZEN

for

UNITED STATES LETTERS PATENT

on

EXPANDABLE STENTS AND METHOD FOR MAKING SAME

Docket No. ACS 35765 (3804.1)

Sheets of Drawing: Four (4)

Attorneys
FULWIDER PATTON LEE & UTECHT
10877 Wilshire Boulevard, 10th Floor
Los Angeles, California 90024

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IN THE UNITED STATES PATENT & TRADEMARK OFFICE

In re the application of)	Examiner: C. Bennett
)	
Inventors: Lilip Lau, William Hartigan,)	Group Art Unit: 3307
John J. Frantzen)	
)	Docket No. ACS 48047 (3807.2)
Division of U.S. Serial No. 08/783,097)	
)	
Filed: Concurrently)	
)	
For: EXPANDABLE STENTS AND)	Los Angeles, California
METHOD FOR MAKING SAME)	April 6, 1998

PRELIMINARY AMENDMENT

Box PATENT APPLICATION
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

This Preliminary Amendment is being filed concurrently with the application that is a division of U.S. Serial No. 08/783,097 filed January 14, 1997, which is a division of 08/556,516 filed November 13, 1995, which is a division of U.S. Serial No. 08/281,790, filed July 28, 1994, now U.S. Patent No. 5,514,154.

IN THE SPECIFICATION:

At page 1, line 2, after the word "application" insert the following:

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04059
00040

is a division of U.S. Serial No. 08/783,097 filed January 14, 1997, which, is a division of U.S. Serial No. 08/556,516, filed November 13, 1995, now U.S. Patent No. 5,603,721, which is a division of U.S. Serial No. 08/281,790, filed July 28, 1994, now U.S. Patent No. 5,514,154, which--.

At page 1, lines 2 and 3, delete "copending"; and line 4, insert --now abandoned-- after the ",".

NE At page 3, line 29, after the word "invention," insert --have a--.

At page 4, line 27, delete "for" and insert --form--.

At page 9, line 36, delete "12" and insert --13--.

At page 10, line 1, delete "11" and insert --12--; line 2, delete "12" and insert --13--; line 10, delete "13" and insert --12--; and line 14, delete "13" and insert --12--.

IN THE CLAIMS:

Please cancel claims 2-24 without prejudice.

Please add the following new claims:

1 25/ A longitudinally flexible stent for implanting in a body lumen, comprising:
a plurality of cylindrical elements which are expandable in the radial direction and
which are connected so as to be generally aligned on a common longitudinal axis; and
at least one weld connection between each cylindrical element to attach the plurality
of cylindrical elements along the common longitudinal axis thereby forming the longitudinally
flexible stent.

2 26. The stent of claim ¹25, wherein at least some of the cylindrical elements are comprised of a generally sinusoidal pattern.

3 27. The stent of claim ²26, wherein the generally sinusoidal pattern of the at least some of the cylindrical elements is continuous.

4 28. The stent of claim ²26, wherein the generally sinusoidal pattern is comprised of a plurality of peaks and a plurality of valleys.

5 29. The stent of claim ⁴28, wherein the plurality of peaks of the cylindrical elements are out of phase.

6 30. The stent of claim ⁵29, wherein the at least one weld connection attaches adjacent cylindrical elements at the peaks.

1 31. The stent of claim ⁶30, wherein the at least one weld connection attaching adjacent cylindrical elements at the peaks are circumferentially offset from one cylindrical element to the next.

8 32. The stent of claim ⁶30, wherein the at least one weld connection attaching adjacent cylindrical elements at the peaks are circumferentially aligned along the stent longitudinal axis.

9
33.

The stent of claim 25, wherein only one weld connection attaches adjacent cylindrical elements to each other.

10
34.

The stent of claim 33, wherein the only one weld connection attaching adjacent cylindrical elements to each other are circumferentially offset from each other.

11
35.

The stent of claim 25, wherein each cylindrical element has a length and a diameter, the length of each cylindrical element being less than the diameter of the cylindrical element when the stent is in an unexpanded and uncrimped configuration.

12
36.

A longitudinally flexible stent for implanting in a body lumen, comprising:
a plurality of cylindrical elements having an undulating pattern of peaks and valleys, the cylindrical elements being generally aligned along a common longitudinal stent axis so that the peaks are out of phase, the peaks of one cylindrical element point toward the peaks of an adjacent cylindrical element; and

a weld connection for attaching one peak of one cylindrical element to an adjacent peak of an adjacent cylindrical element so that the plurality of cylindrical elements are attached along the common longitudinal stent axis thereby forming the longitudinally flexible stent.

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37.

The stent of claim 36, wherein the plurality of cylindrical elements includes only two cylindrical elements.

14
38.

The stent of claim 36, wherein the plurality of cylindrical elements includes more than two cylindrical elements.

Sub B1

39. The stent of claim 36, wherein the plurality of cylindrical elements includes a first cylindrical element, a second cylindrical element and so on up to an N number of cylindrical elements.

40. The stent of claim 39, wherein a first weld connection attaches the first cylindrical element to the second cylindrical element, a second weld connection attaches the second cylindrical element to the third cylindrical element, and so on to the Nth cylindrical element.

41. The stent of claim 40, wherein the first weld connection is circumferentially offset from the second weld connection, the second weld connection is circumferentially offset from the third weld connection, and so on for each of the N cylindrical elements attached by weld connections.

18
42.

The stent of claim 36, wherein each cylindrical element has a length and a diameter, the length of each cylindrical element being less than the diameter of each cylindrical element.

REMARKS

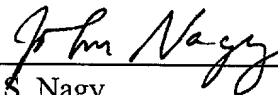
This application is a divisional application of U.S. Serial No. 08/556,516, filed November 13, 1995, for which the issue fee has been paid. Claims 2-24 have been canceled without prejudice, and claims 25-42 have been added by this Preliminary Amendment. No new matter is believed to be presented as all of new claims are fully supported by the specification and drawings. Specifically, weld connections are referenced at page 4, line 17-24, under the heading "Summary of the Invention." Thus, claims 25-42 are pending in the application and early consideration and allowance is solicited.

Several numerical references in the specification have been changed to correct typographical errors. The changes are consistent with the numerical references in the drawings.

Respectfully submitted,

FULWIDER PATTON LEE & UTECHT, LLP

By:



John S. Nagy
Registration No. 30,664

JSN:jeb

10877 Wilshire Boulevard, Tenth Floor
Los Angeles, California 90024
(310) 824-5555

EXPANDABLE STENTS AND METHOD FOR MAKING SAME

RELATED APPLICATIONS

ins A₁

This application is a continuation-in-part of ~~co-~~
~~pending~~ U.S. patent application U.S. Serial No. 08/164,986
filed December 9, 1993, ^{now abandoned} which is a continuation application of
5 U.S. Serial No. 07/783,558 filed October 28, 1991, now
abandoned.

BACKGROUND OF THE INVENTION

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This invention relates to expandable endoprosthesis
devices, generally called stents, which are adapted to be
10 implanted into a patient's body lumen, such as blood vessel, to
maintain the patency thereof. These devices are very useful in
the treatment of atherosclerotic stenosis in blood vessels.

Stents are generally tubular-shaped devices which
function to hold open a segment of a blood vessel or other
15 anatomical lumen. They are particularly suitable for use to
support and hold back a dissected arterial lining which can
occlude the fluid passageway therethrough.

Further details of prior art stents can be found in
U.S. Patent 3,868,956 (Alfidi et al.); U.S. Patent 4,512,338
20 (Balko et al.); U.S. Patent 4,553,545 (Maass et al.); U.S.
Patent 4,733,665 (Palmaz); U.S. Patent 4,762,128 (Rosenbluth);
U.S. Patent 4,800,882 (Gianturco); U.S. Patent 4,856,516
(Hillstead); and U.S. Patent 4,886,062 (Wiktor), which are
hereby incorporated herein in their entirety by reference
25 thereto.

Various means have been described to deliver and
implant stents. One method frequently described for delivering
a stent to a desired intraluminal location includes mounting
the expandable stent on an expandable member, such as a
30 balloon, provided on the distal end of an intravascular
catheter, advancing the catheter to the desired location within
the patient's body lumen, inflating the balloon on the catheter

to expand the stent into a permanent expanded condition and then deflating the balloon and removing the catheter. One of the difficulties encountered using prior stents involved maintaining the radial rigidity needed to hold open a body
5 lumen while at the same time maintaining the longitudinal flexibility of the stent to facilitate its delivery.

What has been needed and heretofore unavailable is a stent which has a high degree of flexibility so that it can be advanced through tortuous passageways and can be readily
10 expanded and yet have the mechanical strength to hold open the body lumen into which it expanded. The present invention satisfies this need.

SUMMARY OF THE INVENTION

The present invention is directed to an expandable
15 stent which is relatively flexible along its longitudinal axis to facilitate delivery through tortuous body lumens, but which is stiff and stable enough radially in an expanded condition to maintain the patency of a body lumen such as an artery when implanted therein.

20 The stent of the invention generally includes a plurality of radially expandable cylindrical elements which are relatively independent in their ability to expand and to flex relative to one another. The individual radially expandable cylindrical elements of the stent are dimensioned so as to be
25 longitudinally shorter than their own diameters. Interconnecting elements or struts extending between adjacent cylindrical elements provide increased stability and a preferable position to prevent warping of the stent upon the expansion thereof. The resulting stent structure is a series
30 of radially expandable cylindrical elements which are spaced longitudinally close enough so that small dissections in the wall of a body lumen may be pressed back into position against the luminal wall, but not so close as to compromise the longitudinal flexibilities of the stent. The individual

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cylindrical elements may rotate slightly relative to adjacent cylindrical elements without significant deformation, cumulatively giving a stent which is flexible along its length and about its longitudinal axis but is still very stiff in the radial direction in order to resist collapse.

The stent embodying features of the invention can be readily delivered to the desired luminal location by mounting it on an expandable member of a delivery catheter, for example a balloon, and passing the catheter-stent assembly through the body lumen to the implantation site. A variety of means for securing the stent to the expandable member on the catheter for delivery to the desired location are available. It is presently preferred to compress the stent onto the balloon. Other means to secure the stent to the balloon include providing ridges or collars on the inflatable member to restrain lateral movement, or using bioresorbable temporary adhesives.

The presently preferred structure for the expandable cylindrical elements which form the stents of the present invention generally circumferential undulating pattern, e.g. serpentine. The transverse cross-section of the undulating component of the cylindrical element is relatively small and preferably has an aspect ratio of about two to one to about 0.5 to one. A one to one aspect ratio has been found particularly suitable. The open reticulated structure of the stent allows for the perfusion of blood over a large portion of the arterial wall which can improve the healing and repair of a damaged arterial lining.

The radial expansion of the expandable cylinder deforms the undulating pattern thereof similar to changes in a waveform which result from decreasing the waveform's amplitude and the frequency. Preferably, the undulating patterns of the individual cylindrical structures are in phase with each other in order to prevent the contraction of the stent along its length when it is expanded. The cylindrical structures of the stent are plastically deformed when expanded (except with NiTi

alloys) so that the stent will remain in the expanded condition and therefore they must be sufficiently rigid when expanded to prevent the collapse thereof in use. During expansion of the stent, portions of the undulating pattern will tip outwardly resulting in projecting members on the outer surface of the expanded stent. These projecting members tip radially outwardly from the outer surface of the stent and embed in the vessel wall and help secure the expanded stent so that it does not move once it is implanted.

10 With superelastic NiTi alloys, the expansion occurs when the stress of compression is removed so as to allow the phase transformation from austenite back to martensite and as a result the expansion of the stent.

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15 The elongated elements which interconnect adjacent cylindrical elements should have a transverse cross-section similar to the transverse dimensions of the undulating components of the expandable cylindrical elements. The interconnecting elements may be formed in a unitary structure with the expandable cylindrical elements from the same
20 intermediate product, such as a tubular element, or they may be formed independently and connected by suitable means, such as by welding or by mechanically securing the ends of the interconnecting elements to the ends of the expandable cylindrical elements. Preferably, all of the interconnecting
25 elements of a stent are joined at either the peaks or the valleys of the undulating structure of the cylindrical elements which ^{form} ~~for~~ the stent. In this manner there is no shortening of the stent upon expansion.

30 The number and location of elements interconnecting adjacent cylindrical elements can be varied in order to develop the desired longitudinal flexibility in the stent structure both in the unexpanded as well as the expanded condition. These properties are important to minimize alteration of the natural physiology of the body lumen into which the stent is
35 implanted and to maintain the compliance of the body lumen which is internally supported by the stent. Generally, the

greater the longitudinal flexibility of the stent, the easier and the more safely it can be delivered to the implantation site.

In a presently preferred embodiment of the invention the stent is conveniently and easily formed by coating stainless steel tubing with a material resistant to chemical etching, removing portions of the coating to expose portions of underlying tubing which are to be removed to develop the desired stent structure. The exposed portions of the tubing are removed by chemically etching from the tubing exterior leaving the coated portion of the tubing material in the desired pattern of the stent structure. The etching process develops smooth openings in the tubing wall without burrs or other artifacts which are characteristic of mechanical or laser machining processes in the small sized products contemplated. Moreover, a computer controlled laser patterning process to remove the chemical resistive coating makes photolithography technology adaptable to the manufacture of these small products. The forming of a mask in the extremely small sizes needed to make the small stents of the invention would be a most difficult task. A plurality of stents can be formed from one length of tubing by repeating the stent pattern and providing small webs or tabs to interconnect the stents. After the etching process, the stents can be separated by severing the small webs or tabs which connect them.

Other features and advantages of the present invention will become more apparent from the following detailed description of the invention. When taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is an elevational view, partially in section, of a stent embodying features of the invention which is mounted on a delivery catheter and disposed within a damaged artery.

FIG. 2 is an elevational view, partially in section, similar to that shown in FIG. 1 wherein the stent is expanded within a damaged artery, pressing the damaged lining against the arterial wall.

5 FIG. 3 is an elevational view, partially in section showing the expanded stent within the artery after withdrawal of the delivery catheter.

10 FIG. 4 is a perspective view of a stent embodying features of the invention in an unexpanded state, with one end of the stent being shown in an exploded view illustrate the details thereof.

FIG. 5 is a plan view of a flattened section of a stent of the invention which illustrates the undulating pattern of the stent shown in FIG. 4.

15 FIG. 6 is a schematic representation of equipment for selectively removing coating applied to tubing in the manufacturing of the stents of the present invention.

20 FIGS. 7 through 10 are perspective views schematically illustrating various configurations of interconnective element placement between the radially expandable cylindrical elements of the stent.

25 FIG. 11 is a plan view of a flattened section of a stent illustrating an alternate undulating pattern in the expandable cylindrical elements of the stent which are out of phase.

FIG. 12 is an enlarged partial view of the stent of FIG. 5 with the various members slightly expanded.

FIG. 13 is a perspective view of the stent of FIG. 4 after it is fully expanded depicting some members projecting radially outwardly.

FIG. 14 is an enlarged, partial perspective view of one U-shaped member with its tip projecting outwardly after expansion.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. 1 illustrates a stent 10 incorporating features of the invention which is mounted onto a delivery catheter 11. The stent generally comprises a plurality of radially expandable cylindrical elements 12 disposed generally coaxially and interconnected by elements 13 disposed between adjacent cylindrical elements. The delivery catheter 11 has an expandable portion or balloon 14 for expanding of the stent 10 within an artery 15. The artery 15, as shown in FIG. 1 has a dissected lining 16 which has occluded a portion of the arterial passageway.

The delivery catheter 11 onto which the stent 10 is mounted, is essentially the same as a conventional balloon dilatation catheter for angioplasty procedures. The balloon 14 may be formed of suitable materials such as polyethylene, polyethylene terephthalate, polyvinyl chloride, nylon and ionomers such as Surlyn® manufactured by the Polymer Products Division of the Du Pont Company. Other polymers may also be used. In order for the stent 10 to remain in place on the balloon 14 during delivery to the site of the damage within the artery 15, the stent 10 is compressed onto the balloon. A retractable protective delivery sleeve 20 as described in co-pending applications Serial No. 07/647,464 filed on April 25, 1990 and entitled STENT DELIVERY SYSTEM may be provided to further ensure that the stent stays in place on the expandable portion of the delivery catheter 11 and prevent abrasion of the body lumen by the open surface of the stent 20 during delivery

to the desired arterial location. Other means for securing the stent 10 onto the balloon 14 may also be used, such as providing collars or ridges on the ends of the working portion, i.e. the cylindrical portion, of the balloon.

5 Each radially expandable cylindrical element 12 of the stent 10 may be independently expanded. Therefore, the balloon 14 may be provided with an inflated shape other than cylindrical, e.g. tapered, to facilitate implantation of the stent 10 in a variety of body lumen shapes.

10 In a preferred embodiment, the delivery of the stent 10 is accomplished in the following manner. The stent 10 is first mounted onto the inflatable balloon 14 on the distal extremity of the delivery catheter 11. The balloon 14 is slightly inflated to secure the stent 10 onto the exterior of
15 the balloon. The catheter-stent assembly is introduced within the patient's vasculature in a conventional Seldinger technique through a guiding catheter (not shown). A guidewire 18 is disposed across the damaged arterial section with the detached or dissected lining 16 and then the catheter-stent assembly is
20 advanced over a guidewire 18 within the artery 15 until the stent 10 is directly under the detached lining 16. The balloon 14 of the catheter is expanded, expanding the stent 10 against the artery 15, which is illustrated in FIG. 2. While not shown in the drawing, the artery 15 is preferably expanded slightly
25 by the expansion of the stent 10 to seat or otherwise fix the stent 10 to prevent movement. In some circumstances during the treatment of stenotic portions of an artery, the artery may have to be expanded considerably in order to facilitate passage of blood or other fluid therethrough.

30 The stent 10 serves to hold open the artery 15 after the catheter 11 is withdrawn, as illustrated by FIG. 3. Due to the formation of the stent 10 from elongated tubular member, the undulating component of the cylindrical elements of the stent 10 is relatively flat in transverse cross-section, so
35 that when the stent is expanded, the cylindrical elements are pressed into the wall of the artery 15 and as a result do not

interfere with the blood flow through the artery 15. The cylindrical elements 12 of stent 10 which are pressed into the wall of the artery 15 will eventually be covered with endothelial cell growth which further minimizes blood flow interference. The undulating portion of the cylindrical sections 12 provide good tacking characteristics to prevent stent movement within the artery. Furthermore, the closely spaced cylindrical elements 12 at regular intervals provide uniform support for the wall of the artery 15, and consequently are well adapted to tack up and hold in place small flaps or dissections in the wall of the artery 15 as illustrated in FIGS. 2 and 3.

FIG. 4 is an enlarged perspective view of the stent 10 shown in FIG. 1 with one end of the stent shown in an exploded view to illustrate in greater detail the placement of interconnecting elements 13 between adjacent radially expandable cylindrical elements 12. Each pair of the interconnecting elements 13 on one side of a cylindrical element 12 are preferably placed to achieve maximum flexibility for a stent. In the embodiment shown in FIG. 4 the stent 10 has three interconnecting elements 13 between adjacent radially expandable cylindrical elements 12 which are 120 degrees apart. Each pair of interconnecting elements 13 on one side of a cylindrical element 12 are offset radially 60 degrees from the pair on the other side of the cylindrical element. The alternation of the interconnecting elements results in a stent which is longitudinally flexible in essentially all directions. Various configurations for the placement of interconnecting elements are possible, and several examples are illustrated schematically in FIGS. 7-10. However, as previously mentioned, all of the interconnecting elements of an individual stent should be secured to either the peaks or valleys of the undulating structural elements in order to prevent shortening of the stent during the expansion thereof.

FIG. 10 illustrates a stent of the present invention wherein three interconnecting elements ~~12~~¹³ are disposed between

radially expandable cylindrical elements ¹²~~11~~. The
interconnecting elements ~~12~~¹³ are distributed radially around the
circumference of the stent at a 120-degree spacing. Disposing
four or more interconnecting elements 13 between adjacent
5 cylindrical elements 12 will generally give rise to the same
considerations discussed above for two and three
interconnecting elements.

The properties of the stent 10 may also be varied by
alteration ¹²of the undulating pattern of the cylindrical
10 elements ~~13~~. FIG. 11 illustrates an alternative stent
structure in which the cylindrical elements are in serpentine
patterns but out of phase with adjacent cylindrical elements.
The particular pattern and how many undulations per unit of
length around the circumference of the cylindrical element ¹²~~13~~,
15 or the amplitude of the undulations, are chosen to fill
particular mechanical requirements for the stent such as radial
stiffness.

The number of undulations may also be varied to
accommodate placement of interconnecting elements 13, e.g. at
20 the peaks of the undulations or along the sides of the
undulations as shown in FIGS. 5 and 11.

In keeping with the invention, and with reference to
FIGS. 4 and 12-14, cylindrical elements 12 are in the form of
a serpentine pattern 30. As previously mentioned, each
25 cylindrical element 12 is connected by interconnecting elements
13. Serpentine pattern 30 is made up of a plurality of U-
shaped members 31, W-shaped members 32, and Y-shaped members
33, each having a different radius so that expansion forces are
more evenly distributed over the various members.

30 As depicted in FIGS. 13 and 14, after cylindrical
elements 12 have been radially expanded, outwardly projecting
edges 34 are formed. That is, during radial expansion U-shaped
members 31 will tip outwardly thereby forming outwardly
projecting edges. These outwardly projecting edges provide for
35 a roughened outer wall surface of stent 10 and assist in
implanting the stent in the vascular wall by embedding into the

vascular wall. In other words, outwardly projecting edges embed into the vascular wall, for example artery 15, as depicted in FIG. 3. Depending upon the dimensions of stent 10 and the thickness of the various members making up the serpentine pattern 30, any of the U-shaped members 31, W-shaped members 32, and Y-shaped members 33 can tip radially outwardly to form a projecting edge 34. It is most likely and preferred that U-shaped members 31 tip outwardly since they do not join with any connecting member 13 to prevent them from expanding outwardly.

The stent 10 of the present invention can be made in many ways. However, the preferred method of making the stent is to coat a thin-walled tubular member, such as stainless steel tubing, with a material which is resistive to chemical etchants, remove portions of the coating to expose underlying tubing which is to be removed but to leave coated portions of the tubing in the desired pattern for the stent so that subsequent etching will remove the exposed portions of the metallic tubing, but will leave relatively untouched the portions of the metallic tubing which are to form the stent. The coated portion of the metallic tube is in the desired shape for the stent. An etching process avoids the necessity of removing burrs or slag inherent in conventional or laser machining process. It is preferred to remove the etchant-resistive material by means of a machine-controlled laser as illustrated schematically in FIG. 6.

A coating is applied to a length of tubing which, when cured, is resistive to chemical etchants. "Blue Photoresist" made by the Shipley Company in San Jose, California, is an example of suitable commercially available photolithographic coatings. The coating is preferably applied by electrophoretic deposition.

To ensure that the surface finish is reasonably uniform, one of the electrodes used for the electrochemical polishing is a doughnut-shaped electrode which is placed about the central portion of the tubular member.

5 The tubing may be made of suitable biocompatible material such as stainless steel, titanium, tantalum, superelastic NiTi alloys and even high strength thermoplastic polymers. The stent diameter is very small, so the tubing from which it is made must necessarily also have a small diameter. Typically the stent has an outer diameter on the order of about 0.06 inch in the unexpanded condition, the same outer diameter of the tubing from which it is made, and can be expanded to an outer diameter of 0.1 inch or more. The wall thickness of the tubing is about 0.003 inch. In the instance when the stent was plastic, it would have to be heated within the arterial site where the stent is expanded to facilitate the expansion of the stent. Once expanded, it would then be cooled to retain its expanded state. The stent may be conveniently heated by heating the fluid within the balloon or the balloon directly by a suitable system such as disclosed in a co-pending application Serial No. 07/521,337, filed January 26, 1990 entitled DILATATION CATHETER ASSEMBLY WITH HEATED BALLOON which is incorporated herein in its entirety by reference. The stent may also be made of materials such as superelastic NiTi alloys such as described in co-pending application Serial No. 07/629,381, filed December 18, 1990, entitled SUPERELASTIC GUIDING MEMBER which is incorporated herein in its entirety by reference. In this case the stent would be formed full size but deformed (e.g. compressed) into a smaller diameter onto the balloon of the delivery catheter to facilitate transfer to a desired intraluminal site. The stress induced by the deformation transforms the stent from a martensite phase to an austenite phase and upon release of the force, when the stent reaches the desired intraluminal location, allows the stent to expand due to the transformation back to the martensite phase.

Referring to FIG. 6, the coated tubing 21 is put in a rotatable collet fixture 22 of a machine controlled apparatus 23 for positioning the tubing 21 relative to a laser 24. According to machine-encoded instructions, the tubing 21 is rotated and moved longitudinally relative to the laser 24 which

is also machine controlled. The laser selectively removes the etchant-resistive coating on the tubing by ablation and a pattern is formed such that the surface of the tube that is to be removed by a subsequent chemical etching process is exposed.

- 5 The surface of the tube is therefore left coated in the discrete pattern of the finished stent.

A presently preferred system for removing the coating on the tubing includes the use an 80-watt CO₂ laser, such as a Coherent Model 44, in pulse mode (0.3 mS pulse length); 48 mA
10 key current and 48 W key power with 0.75 W average power, at 100 Hz; Anorad FR=20; 12.5 Torr; with no assist gas. Low pressure air is directed through the fine focus head to ensure that no vapor contacts the lens. The assist gas jet assembly on the laser unit may be removed to allow a closer proximity of
15 the fine focus head and the collet fixture. Optimum focus is set at the surface of the tubing. Cured photo-resist coating readily absorbs the energy of the CO₂ wavelength, so that it can be readily removed by the laser. A coated 4-inch length of 0.06 inch stainless steel tubing is preferred and four stents
20 can be patterned on the length of tubing. Three tabs or webs between stents provide good handling characteristics for the tubing after the etching process.

The process of patterning the resistive coating on the stent is automated except for loading and unloading the
25 length of tubing. Referring again to FIG. 6 it may be done, for example, using a CNC-opposing collet fixture 22 for axial rotation of the length of tubing, in conjunction with a CNC X/Y table 25 to move the length of tubing axially relative to a machine-controlled laser as described. The entire space
30 between collets can be patterned using the CO₂ laser set-up of the foregoing example. The program for control of the apparatus is dependent on the particular configuration used and the pattern to be ablated in the coating, but is otherwise conventional.

35 This process makes possible the application of present photolithography technology in manufacturing the

stents. While there is presently no practical way to mask and expose a tubular photo-resist coated part of the small size required for making intravascular stents, the foregoing steps eliminate the need for conventional masking techniques.

5 After the coating is thus selectively ablated, the tubing is removed from the collet fixture 22. Next, wax such as ThermoCote N-4 is heated to preferably just above its melting point, and inserted into the tubing under vacuum or pressure. After the wax has solidified upon cooling, it is
10 reheated below its melting point to allow softening, and a smaller diameter stainless steel shaft is inserted into the softened wax to provide support. The tubing is then etched chemically in a conventional manner. After cutting the tabs connecting the stents any surface roughness or debris from the
15 tabs is removed. The stents are preferably electrochemically polished in an acidic aqueous solution such as a solution of ELECTRO-GLO #300, sold by the ELECTRO-GLO CO., Inc. in Chicago, Illinois, which is a mixture of sulfuric acid, carboxylic acids, phosphates, corrosion inhibitors and a biodegradable
20 surface active agent. The bath temperature is maintained at about 110-135 degrees F. and the current density is about 0.4 to about 1.5 amps per in.² Cathode to anode area should be at least about two to one. The stents may be further treated if desired, for example by applying a biocompatible coating.

25 While the invention has been illustrated and described herein in terms of its use as an intravascular stent, it will be apparent to those skilled in the art that the stent can be used in other instances such as to expand prostatic urethras in cases of prostate hyperplasia. Other modifications
30 and improvements may be made without departing from the scope of the invention.

Other modifications and improvements can be made to the invention without departing from the scope thereof.

WHAT IS CLAIMED IS:

1. A longitudinally flexible stent for implanting in a body lumen, comprising:

a plurality of cylindrical elements which are independently expandable in the radial direction and which are interconnected so as to be generally aligned on a common longitudinal axis;

a plurality of connecting elements for interconnecting said cylindrical elements, said connecting elements configured to interconnect only said cylindrical elements that are adjacent to each other; and

an outer wall surface on said cylindrical elements, said outer wall surface having a plurality of outwardly projecting edges which form as said stent is expanded radially outwardly from a first diameter to a second, enlarged diameter.

2. The stent of claim 1, wherein said outer wall surface is substantially smooth when said stent in said first diameter configuration and said outwardly projecting edges form only as said stent is expanded radially outwardly from said first diameter to said second, enlarged diameter.

3. The stent of claim 1, wherein said plurality of outwardly projecting edges extend a distance from said outer wall surface sufficient enough to embed in the vascular wall of the body lumen in order to more firmly attach said stent to the vascular wall.

4. The stent of claim 1, wherein said plurality of cylindrical elements include a plurality of peaks and valleys having a serpentine pattern.

5. The stent of claim 4, wherein said plurality of peaks and valleys include a plurality of U-shaped members, a plurality of Y-shaped members, and a plurality of W-shaped members, some of said U-shaped, Y-shaped, and W-shaped members
5 being interconnected.

6. The stent of claim 5, wherein at least some of said plurality of said U-shaped members tip radially outwardly to form said outwardly projecting edges upon radial expansion of said stent.

7. The stent of claim 5, wherein at least some of said plurality of U-shaped, W-shaped, and Y-shaped members tip radially outwardly to form said outwardly projecting edges upon radial expansion of said stent.

8. The stent of claim 1, wherein said cylindrical elements are capable of retaining their expanded condition upon the expansion thereof.

9. The stent of claim 1, wherein said stent is formed of a biocompatible material selected from the group of materials consisting of stainless steel, tantalum, NiTi alloys, and thermoplastic polymers.

10. The stent of claim 1, wherein said stent is formed from a single piece of tubing.

11. The stent of claim 1, wherein said stent is coated with a biocompatible coating.

12. A longitudinally flexible stent, comprising:
a plurality of cylindrical elements which are independently expandable in the radial direction and which are interconnected so as to be concentrically aligned on a common
5 longitudinal axis; and

a plurality of generally parallel connecting elements for interconnecting said cylindrical elements, said connecting elements configured to interconnect only said cylindrical elements that are adjacent to each other, so that
10 said stent, when expanded radially outwardly, retains its overall length without appreciable shortening.

13. The stent of claim 12, wherein said cylindrical elements are capable of retaining their expanded condition upon the expansion thereof.

14. The stent of claim 12, wherein said radially expandable cylindrical elements in an expanded condition have a length less than the diameter thereof.

15. The stent of claim 14, wherein said stent is formed of a biocompatible material selected from the group consisting of stainless steel, tantalum, super-elastic NiTi alloys, and thermoplastic polymers.

16. The stent of claim 12, wherein said connecting elements between adjacent cylindrical elements are in axial alignment.

17. The stent of claim 12, wherein said connecting elements between adjacent cylindrical elements are circumferentially displaced with respect to said longitudinal axis.

18. The stent of claim 17, wherein the circumferential displacement of said connecting elements between adjacent cylindrical elements is uniform.

19. The stent of claim 12, wherein there are up to four of said connecting elements disposed between adjacent radially expandable cylindrical elements.

20. The stent of claim 12, wherein said radially expandable cylindrical elements and said connecting elements are made of the same material.

21. The stent of claim 12, wherein said stent is formed from a single piece of tubing.

22. The stent of claim 12, wherein the stent is coated with a biocompatible coating.

23. A kit of parts, comprising:

an elongated stent delivery catheter having a proximal end and a distal end, and an expandable member on the distal end; and

5 a longitudinally flexible stent which is adapted to be slidably mounted onto the expandable member of said

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catheter and which comprises a plurality of cylindrical elements which are independently expandable in the radial direction and which are interconnected so as to be
10 concentrically aligned on a common longitudinal axis, wherein each said element is formed of a single elongated structural member forming a serpentine pattern having undulations with peaks and valleys, said elements being interconnected by a plurality of generally parallel interconnecting members between
15 adjacent elements, each said interconnecting member configured to interconnect only said cylindrical elements that are adjacent to each other.

24. A method of transluminally implanting a longitudinally flexible stent in a body lumen, said stent having a plurality of cylindrical elements which are independently expandable in the radial direction and which are
5 interconnected so as to be concentrically aligned on a common longitudinal axis, wherein each said cylindrical element is interconnected a plurality of generally parallel connecting members between adjacent elements, the method comprising the steps of:
10 placing the stent on an expandable portion of a catheter which is adapted to radially expand the stent;
delivering the stent to a desired location within the body lumen;
expanding said cylindrical elements with the
15 expandable portion of the catheter;
contracting the expandable portion of the catheter; and
withdrawing the catheter, leaving the expanded stent implanted in the body lumen.

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ABSTRACT

The invention is directed to an expandable stent for implantation in a body lumen, such as an artery, and a method for making it from a single length of tubing. The stent
5 consists of a plurality of radially expandable cylindrical elements generally aligned on a common axis and interconnected by one or more interconnective elements. The individual radially expandable cylindrical elements consist of ribbon-like material disposed in an undulating pattern. Portions of the
10 expanded stent project outwardly into engagement with the vessel wall to more securely attach the stent.

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FIG. 1

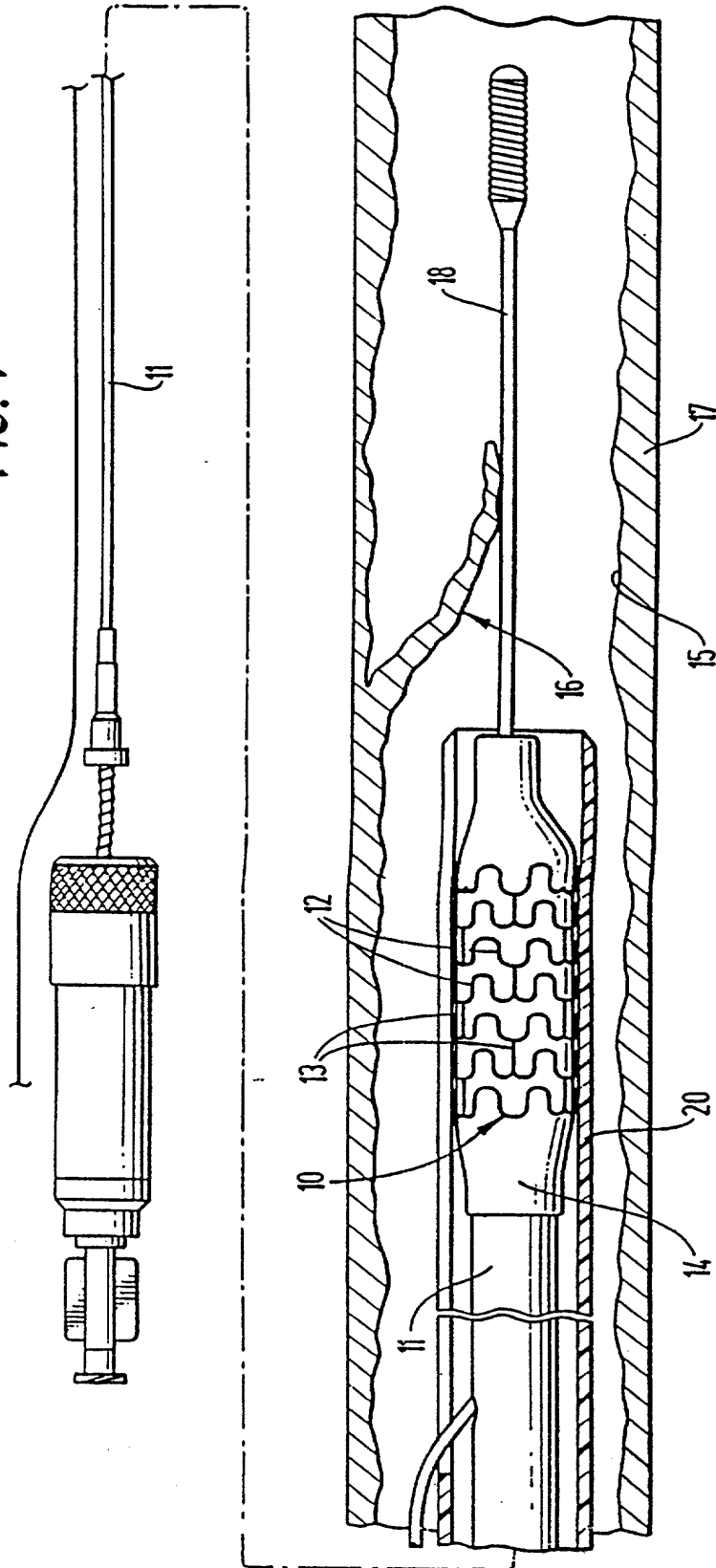


FIG. 2

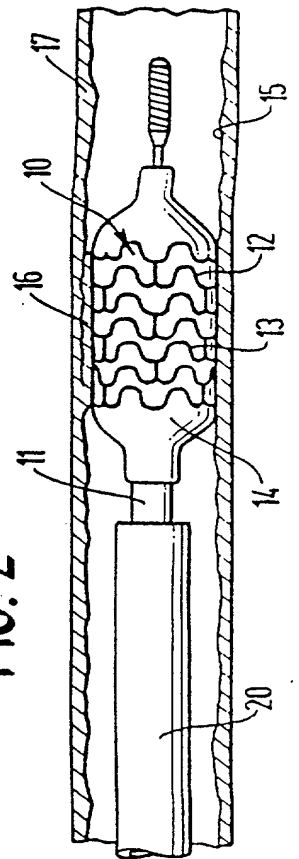
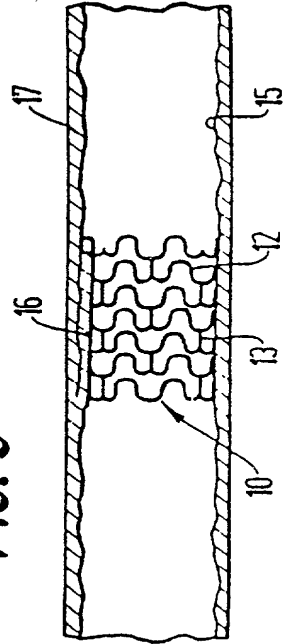


FIG. 3



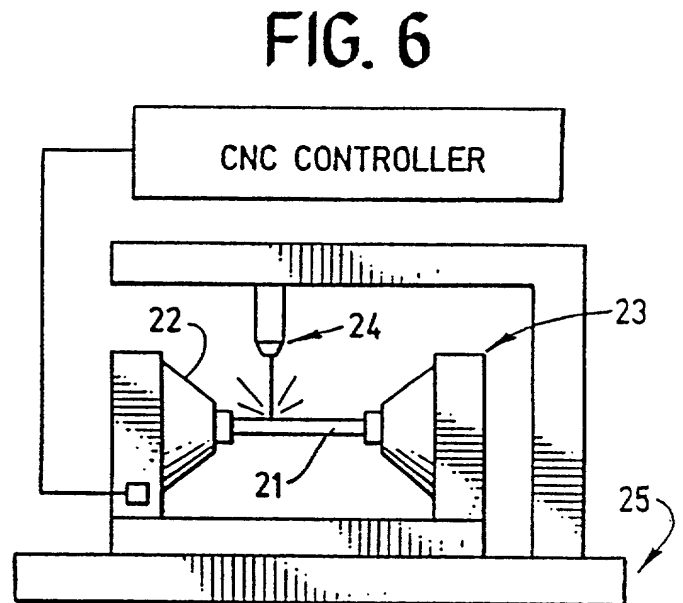
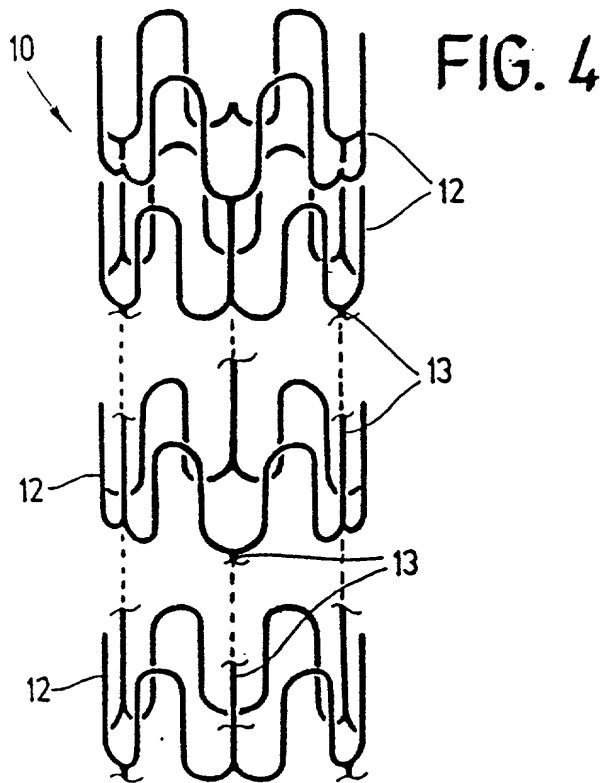


FIG. 5

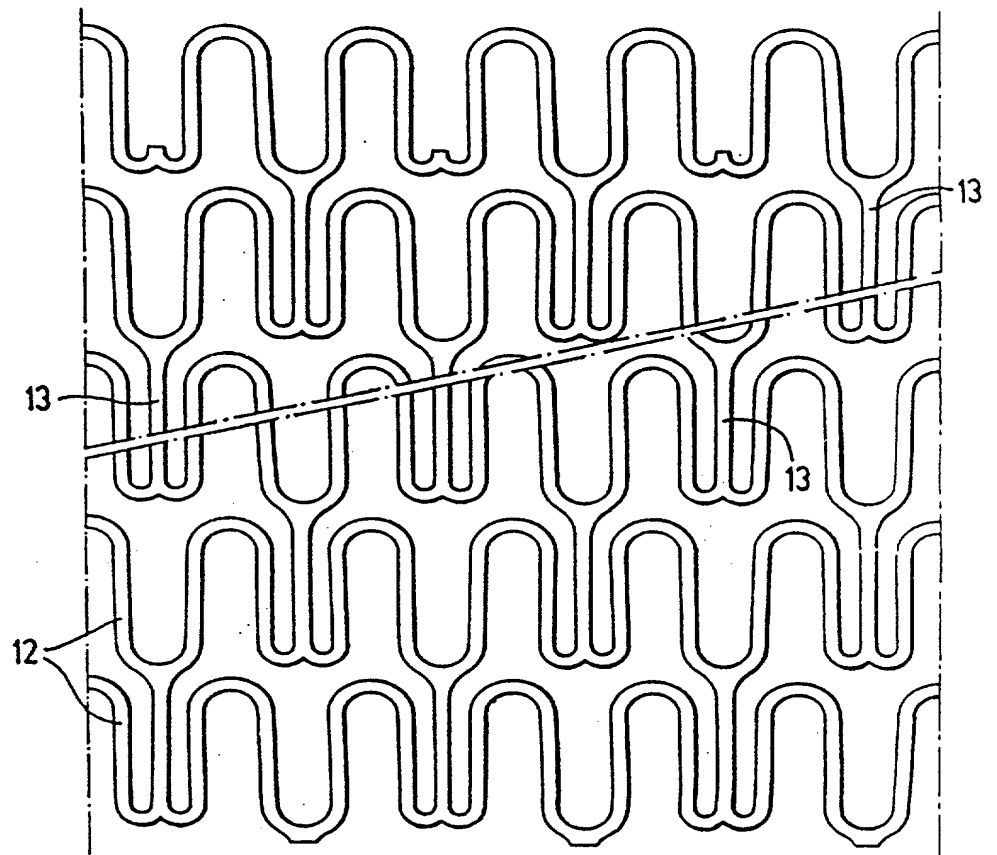


FIG. 7

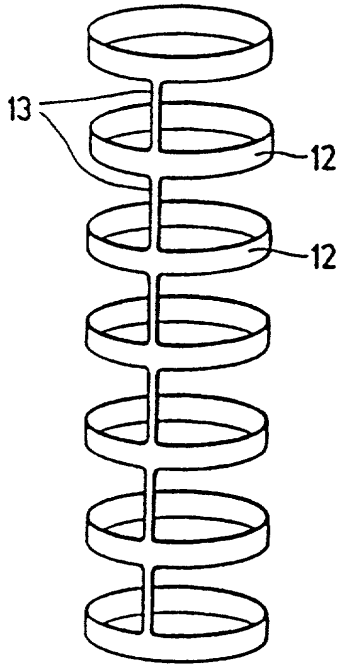


FIG. 8

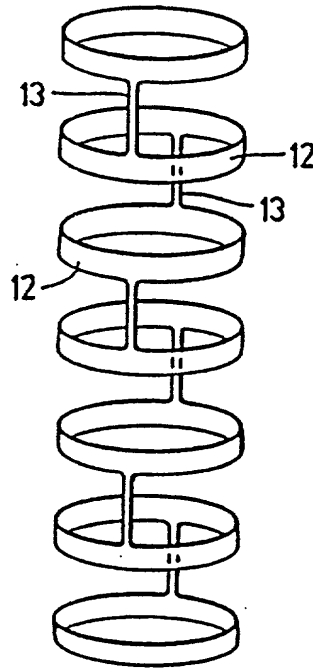


FIG. 9

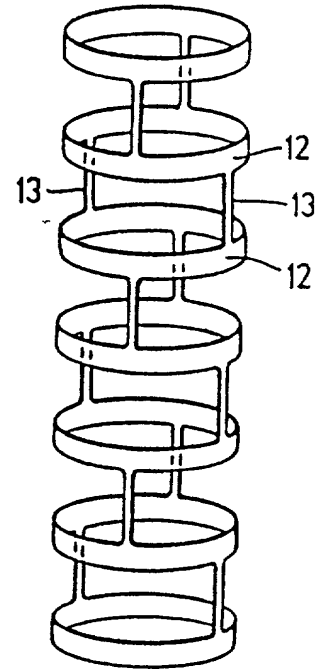


FIG. 10

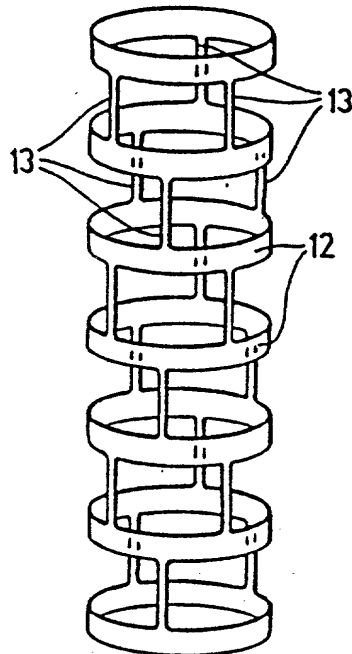
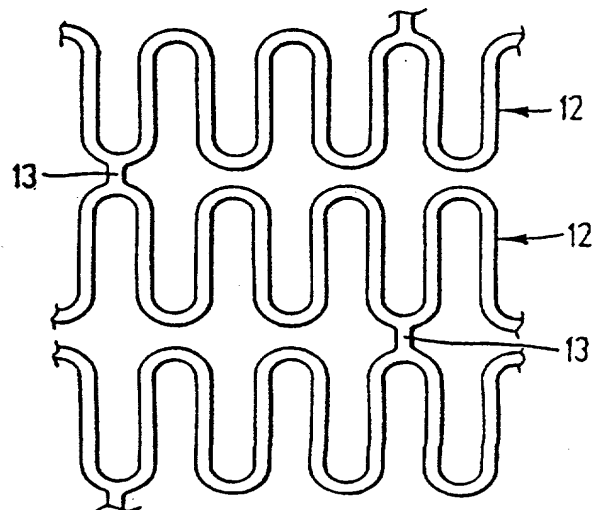


FIG. 11



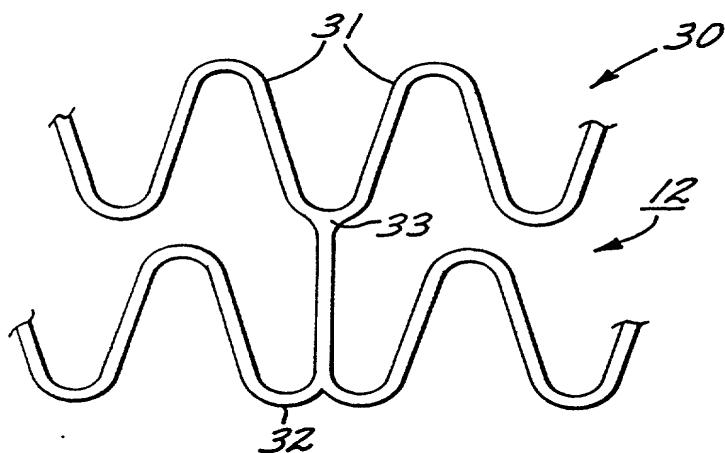


FIG. 12

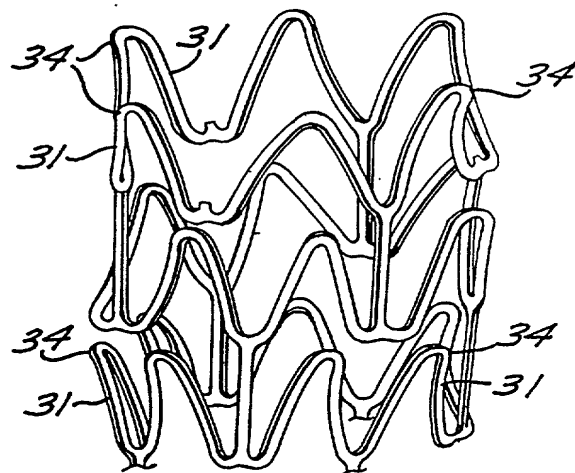


FIG. 13

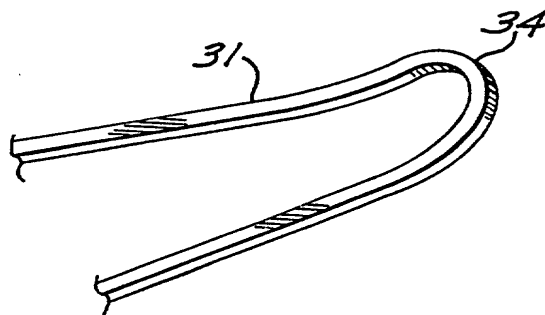
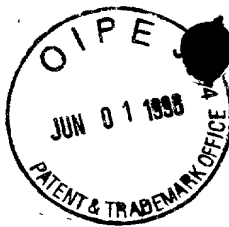


FIG. 14

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DECLARATION AND POWER OF ATTORNEY
FOR PATENT APPLICATION

As the below named inventors, we hereby declare that:

Our residences, post office addresses and citizenships
are as stated below next to our names,

We believe we are original, first and joint inventors
of the subject matter which is claimed and for which a patent is
sought on the invention entitled EXPANDABLE STENTS AND METHOD FOR
MAKING SAME, the specification of which (check one)

_____ is attached hereto
XX was filed on July 28, 1994
Application Serial No. 08/281,790

and was amended on (or amended through) _____
(if applicable)

We hereby state that we have reviewed and understand
the contents of the above-identified specification, including the
claims, as amended by any amendment(s) referred to above.

We acknowledge the duty to disclose information which
is material to the examination of this application in accordance
with Title 37, Code of Federal Regulations, Sec. 1.56(a).

We hereby claim foreign priority benefits under Title
35, United States Code, Sec. 119 of any foreign application(s)
for patent or inventor's certificate listed below and have also
identified below any foreign application for patent or inventor's
certificate having a filing date before that of the application
on which priority is claimed:

Prior Foreign Application(s)			Priority Claimed	
<u>NONE</u>			<u>Yes</u>	<u>No</u>
Number	Country	Day/Month/Year filed		

We hereby claim the benefit under Title 35, United States Code, Sec. 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, Sec. 112, we acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, Sec. 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

<u>NONE</u>		
Appln. Serial No.	Filing Date	Status (patented, pending abandoned)

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

We hereby appoint the following attorneys to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

CRAIG B. BAILEY, Registration No. 28,786, RICHARD A. BARDIN, Registration No. 20,365, GILBERT G. KOVELMAN, Registration No. 19,552, and JOHN S. NAGY, Registration No. 30,664. Direct all telephone calls to John S. Nagy at telephone No. (310) 824-5555.

Address all correspondence to:

FULWIDER, PATTON, LEE & UTECHT
10877 Wilshire Boulevard
Tenth Floor
Los Angeles, California 90024

Full name of first inventor: Lilip Lau

Inventor's signature: _____

Date: _____, 1994

Residence: Sunnyvale, California

Citizenship: United States of America

Post Office Address: 1132 South Sage Court
Sunnyvale, California 94087

Full name of second inventor: William M. Hartigan

Inventor's signature:  _____

Date: 7-27- _____, 1994

Residence: Fremont, California

Citizenship: United States of America

Post Office Address: 4547 Renato Court
Fremont, California 94536

Full name of third inventor: John J. Frantzen

Inventor's signature: _____

Date: _____, 1994

Residence: Copperopolis, California

Citizenship: United States of America

Post Office Address: 424 Poker Flat Road
Copperopolis, California 95228

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DECLARATION AND POWER OF ATTORNEY
FOR PATENT APPLICATION

As the below named inventors, we hereby declare that:

Our residences, post office addresses and citizenships
are as stated below next to our names,

We believe we are original, first and joint inventors
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MAKING SAME, the specification of which (check one)

_____ is attached hereto

XX was filed on July 28, 1994

Application Serial No. 08/281,790

and was amended on (or amended through) _____
(if applicable)

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on which priority is claimed:

Prior Foreign Application(s)

Priority Claimed

NONE

Number

Country

Day/Month/Year filed

Yes

No

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Full name of second inventor: William M. Hartigan

Inventor's signature: _____

Date: _____, 1994

Residence: Fremont, California

Citizenship: United States of America

Post Office Address: 4547 Renato Court
Fremont, California 94536

Full name of third inventor: John J. Frantzen

Inventor's signature:  _____

Date: 7/12/94, 1994

Residence: Copperopolis, California

Citizenship: United States of America

Post Office Address: 424 Poker Flat Road
Copperopolis, California 95228

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